

## Kansas Medical Assistance Program Drug Utilization Review Bulletin



## The Use of OTC Cough and Cold Preparations in Children

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The cold is one of the most common childhood illnesses and is the second most common diagnosis made in physician offices. Children experience an average of six to eight colds a year. Cold symptoms may include; nasal congestion, rhinorrhea, cough, and restless nights. Many parents use over-the-counter (OTC) cold medications to help relieve symptoms, but are unaware of the risks involved with their use.

The Food and Drug Administration (FDA) recommends that over-the counter (OTC) cough and cold products not be used for infants and children. The use of these products may result in serious and potentially life threatening side effects.

During the years of 2004-2005, the Centers for Disease Control and Prevention estimated that 1,519 children less than two years of age were treated in U.S. emergency departments for adverse effects associated with cough and cold products.<sup>2</sup> Reported adverse effects have included convulsions, tachycardia, agitation, decreased levels of consciousness, and death.<sup>3,4</sup> Many of these adverse effects are the result of dosing errors, unintentional ingestion, and drug-drug or drug-disease state interactions.

In response to the FDA's recommendation, several preparations that were specifically marketed for use in children less than 2 years of age have already been voluntarily removed from the market by manufacturers. However, providers should keep in mind that parents may use other cough and cold products, intended for use in older children or adults, in their younger children.

The FDA is currently studying the safety and efficacy of the use of OTC cough and cold products in patients between two and eleven years of age. FDA recommends the following to parents regarding the use of OTC cough and cold medications in children two years of age and older until the investigation is complete.

- Checking the active ingredients section of the DRUG FACTS label which explains the intended treatment.
- Avoid duplication of active ingredients when administering more than one OTC cough and cold product.
- Follow dosing instructions carefully—call a healthcare professional if any questions arise.

- Only use the dosing spoons or cups that come with the medication or designed specifically to administer medications.
- Note: A teaspoon from a set of table service does not provide accurate measurement of medication.
- Store all medications out of the reach of children.
- If available, choose an OTC cough and cold product that has a childproof safety cap.
- OTC cough and cold products only help relieve symptoms, but do not help the child to get better.
- Do not use these medications to make your child sleepy.
- Call a healthcare professional if there are any questions about using cough and cold medications in children two years of age or older.

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## References:

- 1. Sismasek M and Blandino DA. Treatment of the common cold. Am Fam Physician 2007;75:515-20.
- 2. Infant deaths associated with cough and cold medications-two states, 2005. MMWR Morb Mortal Wkly Rep. 2007;56(1):1-4
- 3. Gunn VL, Taha SH, Liebelt EL, et al. Toxicity of over-the-counter cough and cold medications. Pediatrics 2001;108(3):e52. Accessed May 29, 2008 at <a href="http://pediatrics.aappublications.org/cgi/content/full/108/3/e52">http://pediatrics.aappublications.org/cgi/content/full/108/3/e52</a>.
- Food and Drug Administration. FDA news. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01778.html. Accessed on June 29, 2008.
- 5. American Academy of Pediatrics. Committee on Drugs. Use of codeine- and dextromethorphan-containing cough remedies in children. Pediatrics 1997;99(6):918-920.